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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,614	01/12/2001	Francis Darro	P66243US0	6005

136 7590 08/23/2002

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EXAMINER

GOLDBERG, JEROME D

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/23/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,614

Applicant(s)

DARRO ET AL.

Examiner

Jerome D Goldberg

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Claims 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper Nos. 6 and 8.

Applicant's remarks use noted but the enhanced combination with genistein and cytotoxic agent will support a separate patent from the genistein compositions alone. Applicants on page 20, lines 12-17 of the specification clearly obtain any enhanced survival time, which is "longer than that obtained with the treatment involving genistein or the cytotoxic agents used alone". Therefore, the restriction requirement is deemed proper and made Final.

Applicant's elected the enhanced combination of genistein and vin~~cr~~^{cr}ristin for examination as the merits. Claims 12-15 are being examined as they read in the elected enhanced combination.

Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific cytotoxic agent disclosed and elected, does not reasonably provide enablement for the term "cytotoxic agent". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The term "cytotoxic agent" in claims 12-15 lacks clear exemplary support in the specification as filed. Changing the term to the specific cytotoxic agent elected would overcome this rejection.

Claims 12 and 13 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific isoflavonoid or analogue of the chromone type disclosed and elected, does not reasonably provide enablement for the term "an isoflavonoid or an analogue of the chromone type". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The term "an isoflavoniod or an analogue of the chromone type" in claims 12 and 13 lacks clear exemplary support in the specification as filed. Changing the term to the specific isoflavonoid or chromone type elected would overcome this rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Weber et al patent taken with the WO 97/46531 publication.

The Weber et al patent teaches "Genistein injected into neonatal rats reduces dimethylbenz(a) anthracene (DMBA)-induced mammary tumor induction by about 50%". (column 1, lines 47-49). The WO 97/46531 publication teaches applicant's vincristine being combined with cytotoxic (see claim 20, page 27) agent for treating mammary tumor (claim 4, page 4) in human (claim 22, page 27). The patent and publication do not teach the combination together.

Accordingly, one skilled in this art could find ample motivation from the prior art supra to combine the well known anti-mammary tumor agents together where the results obtained thereby are no more the additive effects of the ingredients. In re Sussman, 1943 C.D. 518. The data in the specification including Table III on page 20 shows an unexpected and/or unobvious for a dosage of 20 mg/kg of genistein with 0.63 mg/kg of vincristine but the instant claim fail to recite the amount of the agents being employed. Moreover, the instant are directed to "comprises" which would include other agents.

Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

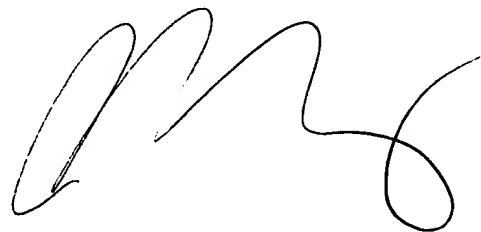
Claim 12-15 should recite the amount of the cytotoxic^c agent being employed with the isoflavanoid agent. Without an amount, it is not apparent that the enhanced effect is obtained. The term "at least one" in claims 12-15 is indefinite in failing to recite an upper limit. Correction is required. The term "chosen from" in claims 14 and 5 should recite "selected from the group consisting of".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday- Thursday 9 am - 3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-4556 for regular communications and (703) 3053592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg:mv
August 21, 2002



JEROME D. GOLDBERG
PRIMARY EXAMINER